



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/538,709 | 10/03/1995 | DOUGLAS P. CERRETTI | 2826-A | 6869 |

22932 7590 01/31/2005

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 08/538,709 | Applicant(s) CERRETTI, DOUGLAS P. | |
| | Examiner Regina M. DeBerry | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-61 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 53-57 is/are allowed.
6) ☒ Claim(s) 29-52 and 58-61 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

The amendment filed 14 October 2004 has been entered in full. Claims 29-61 are under examination.

Applicant has complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. The request for corrected filing receipt filed 03 September 2004 has been entered. The instant application is a CIP of application, 08/318,393, now abandoned, filed 05 October 1994.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102 (e)

Claims 29, 32, 35, 38, 41, 44, 47 and 50 remain rejected under 35 U.S.C. 102(e) as being anticipated by Flanagan *et al.*, U S Patent No. 5,795,734. The basis for this rejection is set forth at pages 3-4 of the previous Office Action (23 July 2004).

Applicant states that the effective filing date of the present application is October 5, 1994 and that the date is only 16 days after the possible filing date of the '734 patent. Applicant asserts that the provision of 37 C.F.R. 1.608(a) apply. Applicant cites the instant provision. Section 1.608(a) states that when the effective filing date of an application is three months or less after the effective filing date of a patent, before an interference will be declared, either the Applicant or the Applicant's attorney or agent of record shall file a statement alleging that there is a basis upon which the Applicant is entitled to a judgment relative to the patent. Applicant requests withdrawal of the 102(e)

Art Unit: 1647

rejection and requests that an interference be declared between the present application and the '734 patent.

Applicant's arguments have been fully considered and are deemed partly persuasive. The Examiner agrees that the instant application has an effective filing date of 05 October 1994. However, Applicant is respectfully reminded of the new rules for patent interferences. Part 41, Practice Before the Board of Patent Appeals and Interferences, 37 CFR Ch.1 (7-15-2004 Edition). The new rules require a showing under 41.202(d). Please see section Subpart E-Patent Interferences, sections 41.200-41.208, especially section 41.202. The instant rejection will be maintained

Claim Rejections - 35 USC 135(b)

Claims 30, 31, 33, 34, 36, 37, 39, 40, 42, 43, 45, 46, 48, 49, 51, 52, 58-61 remain rejected under 35 U.S.C. 135(b) as not being made prior to one year from the date on which U.S. Patent No. 5,795,734 was granted. The basis for this rejection is set forth at page 4 of the previous Office Action (23 July 2004).

Applicant cites the MPEP, 35 USC 135(b). Applicant argues that at least one claim that was pending in the present application prior to the expiration of one year from the issue date of the '734 patent (prior to August 1999), was for substantially the same subject matter as at least one of the claims of the patent. Applicant cites claim 2 of the instant application, "an isolated DNA sequence encoding a LERK-6 polypeptide that binds hek/elk and that is at least 90% identical with the sequence of amino acid residues selected from the group consisting of 1 to 184 of SEQ ID NO: 2 and 1 to 104 of

SEQ ID NO: 8". Applicant argues that claim 2 was pending in the application in that form until it was amended in an amendment filed September 28, 1999, to include conditions for calculating percent identity. Applicant asserts that claim 2 of the present application was for substantially the same subject matter as claim 1 of the '734 patent.

Applicant asserts that claim 2 of the instant application recited an isolated DNA sequence, which is an isolated nucleic acid' according to claim 1 of the '734 patent. Applicant argues that amino acids 1 to 184 of SEQ ID NO: 2 according to claim 2 of the present application are identical to amino acids 26 to 209 of SEQ ID NO: 2 according to claim 1 of the '734 patent. Applicant concludes that a polypeptide that is at least 90% identical with the sequence of amino acid residues 1 to 184 of SEQ ID NO: 2 is a polypeptide sequence that is at least 70% identical to an amino acid sequence of SEQ ID NO: 2 and portions thereof according to claim 1 of the '734 patent. Applicant argues that a polypeptide that binds hek/elk according to claim 2 of the present application is a polypeptide that specifically binds to an EPH-type receptor according to claim 1 of the '734 patent.

Applicant's arguments have been fully considered but are not deemed persuasive. Claim 1 of the '734 patent recites, "an isolated nucleic acid encoding a recombinant polypeptide, which polypeptide comprises and Elf-1 polypeptide sequence **at least 70 percent identical** to an amino acid sequence selected from the group consisting of SEQ ID NOs. 2 and 4, and portions thereof, and which Elf-1 polypeptide specifically binds to an EPH-type receptor". SEQ ID NO:2 of '734 patent is 209 amino acids. Claim 2 of the instant application recites, "an isolated DNA sequence encoding a

Art Unit: 1647

LERK-6 polypeptide that binds hek/elk and that is **at least 90% identical** with the sequence of amino acid residues selected from the group consisting of 1 to 184 of SEQ ID NO: 2 and 1 to 104 of SEQ ID NO: 8". SEQ ID NO:2 of the instant application is 184 amino acids. Claim 1 of the '734 patent allows for a maximum of 30% nonidentical sequence comprising 209 amino acids. Claim 2 of the instant application allows for a maximum of 10% nonidentical sequence comprising 184 amino acids. The two claims are not substantially the same. Secondly, claims 30, 31, 33, 34, 36, 37, 39, 40, 42, 43, 45, 46, 48, 49, 51, 52, 58-61 are drawn to specific fragments of SEQ ID NO:2 (protein) and SEQ ID NO:1 (DNA). There was no support for these contemplated fragments.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

Claims 29-52 and 58-61 are rejected.

Claims 53-57 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

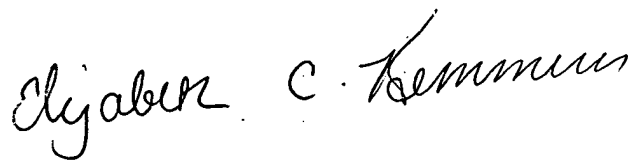
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RMD
1/21/05



ELIZABETH KEMMER
PATENT EXAMINER